

## **REMARKS**

Reconsideration of this application is requested. Claims 1-8, 11-25 and 62-66 are in the case.

### **I. SPECIFICATION**

The specification has been amended to include customary headings. A new Abstract based on amended Claim 1 is presented on a separate sheet attached to this response.

In response to the suggestion that the subject matter of this applications admits of illustration, a proposed drawing is attached. The specification has been amended to include a brief description of this drawing. A formal drawing will be submitted once the application is in condition for allowance and the Examiner has approved the proposed drawing. No new matter is entered.

### **II. CLAIM OBJECTIONS**

Claims 1-25 have been objected to in view of the spelling of the word "fibre." The claims have been amended to insert the American spelling "fiber."

**III. THE 35 U.S.C. 112, SECOND PARAGRAPH, REJECTION**

Claim 25 stands rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite in view of the expression "recrystallized melt phase." In response, this objection has received attention by virtue of the proposed amendments to Claim 1 where the recrystallized melt phase is defined as being of the same polymer as the fibres, where the recrystallized melt phase consists of from 5% to 50% by weight of the polymeric material and has a melting point less than that of the molecular weight oriented fiber. Claim 1 further specifies that the recrystallized melt phase joins areas of adjacent fibers to form a network or continuous three-dimensional matrix which binds the fibers and filler together. These features are readily determinable by examination of the product using differential scanning calorimetry and electron microscopy. Basis for the amendments are particularly to be found in previous Claims 32 and in the disclosure at page 5, lines 9-19.

Withdrawal of the outstanding 35 U.S.C. 112, second paragraph, rejection is believed to be in order. Such action is respectfully requested.

#### IV. THE ANTICIPATION REJECTIONS

Claims 1-6, 9-18 and 22-25 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 4,662,887 to Turner. That rejection is respectfully traversed.

As now claimed, the invention is directed to a composite material comprising a particulate inorganic filler material and a fibrous polymeric material. The fibrous polymeric material comprises molecular oriented polymeric fibers and a recrystallized melt phase of the same polymer as the fibers. The recrystallized melt phase consists of from 5% to 50% by weight of the polymeric material and has a melting point less than that of the molecularly oriented fiber. The recrystallized melt phase joins areas of adjacent fibers to form a network or continuous three-dimensional matrix which binds the fibers and filler together.

Turner does not anticipate the composite material as now claimed. There is no disclosure in Turner of a polymeric material which is 5 to 50% by weight recrystallized melt phase binding together fibers of the same polymeric and a particulate filler. Column 3, beginning at line 40 of Turner describes how reinforcement of polymers may be achieved. Turner discusses reinforcement of polymers by fibers, and indicates that the fiber component of a high modulus device may be any of the range of fiber materials that are available and are compatible with the polymer matrix with which they are to be associated and

which are capable of imparting the desired properties. The Examples are provided at column 3, beginning at line 49 and are of materials which are **different** to the material of the polymer. This is to be contrasted with the presently-claimed material which includes both matrix and fibrous portions of the **same** polymer.

In addition, Turner describes that the inorganic filler should not be exposed to a living tissue but should be covered by compatible polymer (see column 4, lines 13-24). This conveys to the reader that the filler is not biocompatible. Turner refers to the use of high modulus polyethylene with the PEEK. However, this is not possible if the fiber structure is to be retained, as PEEK must be softened at 380 °C . This is a temperature at which all of the polyethylene would convert to melt phase, with the resultant lack of any oriented FDPE fiber in the finished product.

For all of the above response, it is believed that the invention as now claimed is not anticipated by Turner. Withdrawal of the anticipation based on that reference is accordingly respectfully requested.

Claims 19-21 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by , in the alternative, under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Turner. That rejection is respectfully traversed.

Turner does not suggest the presently claimed . Claims 19-21 are dependent, either directly or indirectly on Claim 1 and thereby incorporate all of the features of Claim 1, which are not anticipated or suggested by Turner.

The disclosure of Turner demonstrates the inadequacy of the technical content with regard to at least some of the embodiments described. At column 1, lines 37-52, it is noted that materials that have too high a modulus inhibit bone healing. Examples 3 and 4 of Turner have a modulus of 41 and 47 GN/n<sup>2</sup>, respectively, which is above the presently preferred range, and it is reported (column 7, lines 52-55) that these show non-benign response about 30 weeks in dogs. Example 1, in contrast, has a lower modulus than that of the preferred range (3.8).

A person of ordinary skill could gain no insight from these examples. There is no suggestion or disclosure of any particular favorable ductility. The presently claimed materials allow closer matching of bioactivity, modulus, strength and ductility to that of cortical bone, a property which is not suggested by or could be inferred from the Turner disclosure.

Withdrawal of the outstanding anticipation/obvious rejection based on Turner is respectfully requested.

**V. THE OBVIOUSNESS REJECTION**

Claims 7 and 8 stand rejected under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Turner in view of U.S. Patent No. 4,842,604 to Dorman. That rejection is respectfully traversed.

Claims 7 and 8 are each indirectly dependent on Claim 1 and thereby incorporate all of the patentable features of Claim 1. Turner does not suggest the subject matter of Claim 1 for the above-discussed reasons. The deficiencies of Turner are certainly not cured by Dorman. Dorman is relied upon in view of its alleged disclosure relating to the creation of composite material utilizing apatite and hydroxyapatite as a biocompatible material. Other than that disclosure, Dorman is irrelevant so far as the presently claimed composite materials are concerned. Turner relates to the use of polymer with fibrous or particulate inorganic reinforcement. The presently claimed invention, on the other hand, is based on the use of a polymeric material that includes its own reinforcement. Thus, the present invention allows for the use of a filler which is not itself a reinforcement but which is preferably a bioactive, biocompatible filler such as hydroxyapatite. Turner suggests the use of carbon fibers as a strong reinforcement material, and there would have been no motivation for one of ordinary skill, even in light of Dorman, to replace the essential "inorganic reinforcements" of Turner by non-reinforcing hydroxyapatite.

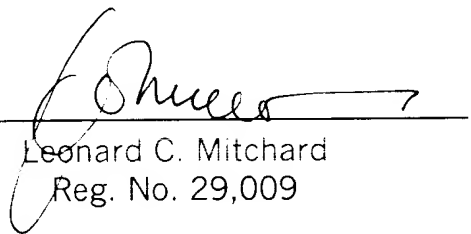
In light of the above, it is clear that Turner and Dorman are non-analogous art, and would not have been resorted to in combination by one of ordinary skill, as suggested by the Examiner. There would have been no motivation to combine the disclosures of Turner and Dorman in the context of the present invention, and even if that combination had been attempted (it is believed that that would not have occurred), it is clear that the presently claimed invention would not have resulted or have been rendered obvious thereby. Absent any motivation to combine Turner and Dorman, it is clear that a *prima facie* case of obviousness is not generated against any of the claims in this application, and in particular against Claims 7 and 8. Withdrawal of the obviousness rejection based on Turner and Dorman is accordingly respectfully requested.

Allowance of the application is awaited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
Leonard C. Mitchard  
Reg. No. 29,009

LCM:lks  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201-4714  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100  
Attachment: Drawing